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10/035,985	12/31/2001	Xingwu Wang	XW-33	3623

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EXAMINER

YUAN, DAH WEI D

ART UNIT PAPER NUMBER

1745

DATE MAILED: 09/21/2004

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AND INTERFERENCES

Application Number: 10/035,985

Filing Date: December 31, 2001

Appellants: Xingwu Wang, Chaonan Chen, Huihui Duan

MAILED
SEP 21 2004
GROUP 1700

Peter J. Mikesell
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed August 6, 2004.

(1) *Real party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellants' statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

The rejections of claims 1-3 and 6-18 stand or fall together as stated in the brief.

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

“Biochemistry” by Donald Voet and Judith Voet, John Wiley & Sons (1990), pp. 618-621.

(10) *Grounds of Rejection*

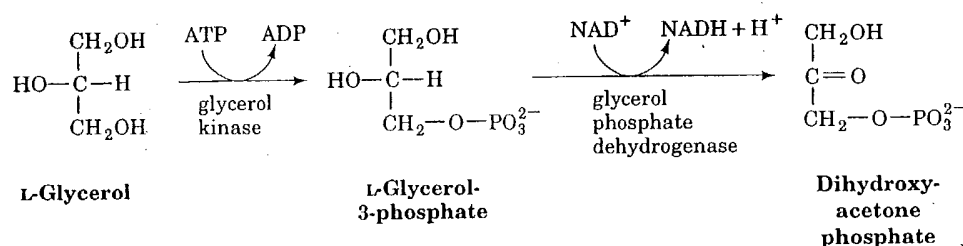
The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-3,6-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, which was described in the final rejection dated July 13, 2004. The rejection is repeated below for convenience.

Claim 1 recites an implantable fuel cell assembly comprising means for converting fat to glycerol and fatty acid, in which lipase enzymes is the preferred embodiment that catalyzes the hydrolysis of fats to glycerol and fatty acids. See instant disclosure, page 7, line 18 to page 8, line 2. However, it is well known in the art that enzymatic reaction *in vivo* is a complex process

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which depends on many factors, including but not limited to temperature, pH and salt concentration. From the viewpoint of lipid metabolism, lipase enzyme, as are many proteins, is rapidly denatured. It is unclear how the lipase enzymes can effectively be replenished and/or regenerated to retain the conversion process. The disclosure does not discuss or suggest the source of the lipase enzymes and how the degradation of the enzymes might affect the process. Moreover, fatty acids is known to form micelles that act as detergents to disrupt protein and membrane structure and would therefore be toxic to humans if the concentration is higher than 10^{-6} M. See "Biochemistry" by D. Voet and J. Voet, p. 621. The disclosure does not elaborate or even mention the potential catastrophic events to the recipient of such implant. This raises doubts about the feasibility and practicality for the use of fatty acid as an intermediate product in the production of hydrogen fuel. More importantly, it is known in the art that glycerol can be broken down to become dihydroxyacetone phosphate and hydrogen proton (H^+) as shown in the reaction below. See "Biochemistry" by D. Voet and J. Voet, p. 620.



In contrary, the instant disclosure teaches the use of molecular hydrogen (H_2) as fuel to produce electricity as recited in claim 1 and Figure 1. The difference in describing the chemical

and biological characteristic of the fuel does not enable a person of ordinary skill in the art to make and use the claimed invention.

(11) Response to Argument

Appellant asserts that Examiner violates the theory of compact prosecution by issuing a second non-final Office Action.

This assertion does not appear to involve an appealable matter. Examiner acknowledges the fact that the prosecution of the instant case has been extended. As stated in the prosecution history in the Appeal Brief (see page 4, lines 6-14), Applicants chose to cancel two claims to overcome the basis of final rejections following the notification of defective appeal brief dated May 3, 2004. The cancellation renders the original ground of rejections moot and prompts the second non-final Office Action dated July 13, 2004.

Appellant argues that Examiner should never make the determination based on personal opinion as to the enablement of the invention.

During the course of the prosecution, consultations and meetings were held with examiners who are more familiar with the subject matter of the invention. Determinations of enablement are also based upon the current state of knowledge in the field of biochemistry. The rejections have full support in the record, including textbook sources, such as Biochemistry by Voet et al.

Appellant argues that Examiner has failed to establish that the specification does not teach one how to practice the invention. Instead the Examiner has cited elements of the specification and presents arguments which seem to focus on the commercial viability of the invention.

The independent claim 1 is construed as a claim having functional limitations, which are associated with elements having a particular capability. When a claim limitation is construed as a means plus function limitation, the Examiner looks to the specification for the corresponding structure and equivalents thereof. The limitation "means for converting fat to glycerol and fatty acid" in claim 1 is understood as "the use of lipase enzymes to catalyze the hydrolysis of fats to glycerol and fatty acids". See page 7, line 18 to page 8, line 2. The applicants continue to include five U.S. patents to bolster their assertions about the functionality and preparation of the enzymes. However, none of these patents as well as the disclosure discuss the metabolic and biochemical aspects of the enzymes when they are incorporated in a living human body. Lipase enzymes are known to rapidly denatured at interfaces including lipid-water interfaces. Colipase, a pancreatic protein, is typically used to inhibit the surface denaturation of lipase and anchors it to the lipid-water interface. See "Biochemistry" by Voet et al., pp. 619, right column, third paragraph,. It is the position of the examiner that the sources and preservation of the lipase enzymes are essential to enable the use and operation of an implantable fuel cell. The instant specification has not enabled a person skilled in the art to make and use the claimed invention without undue experimentation.

Appellant argues that the safety issue raised by the Examiner is not a statutory ground for an enablement rejection.

Appellant's arguments are persuasive and the reasons for concern are withdrawn.

Appellants do not agree how the teachings of the instant disclosure, which teaches the decomposition of glycerol into gaseous hydrogen, are contrary to the equation shown by the Examiner.

To facilitate the discussion, a brief description of how a fuel cell works is as follows. Hydrogen or a hydrogen-rich gas is supplied through a flow path to the anode side of a fuel cell while oxygen (such as in the form of atmospheric oxygen) is supplied through a separate flow path to the cathode side of the fuel cell. After the gaseous fuel and oxygen are routed through their respective flow paths and pass through the interstices of corresponding porous electrodes, they encounter a layer of catalyst. Upon contact with the catalyst on the anode, the hydrogen is ionized and migrates through a membrane situated between the anode and cathode of each fuel cell. The ionized hydrogen then combines with oxygen that has been ionized at the cathode. Together, the ionized hydrogen and oxygen form water and electrons are extracted from the reaction to generate electricity. It is evident that gaseous hydrogen is required as the reactant in the fuel cell. This is also disclosed in the instant disclosure in which H_2 is indicated as the reactant for the fuel cell after the conversion of some or all of the glycerol into hydrogen. See instant disclosure, page 15, lines 8-11; Figure 1. On the other hand, Voet et al. teach the glycerol


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is broken down to become dihydroxyacetone phosphate and hydrogen proton (H^+) as shown in the reaction as described above in Section (10).


Hydrogen protons are fundamentally different from gaseous hydrogen where the former has to be combined into H_2 by using a combiner, which is essentially made up of electron donors, such as zinc, magnesium copper. The specification does not reconcile the discrepancy between the hydrogen required for the operation of the fuel cell and the hydrogen proton produced from the conversion of glycerol. It is, therefore, concluded that the claim using means plus function limitations without corresponding disclosure of specific structures commensurate with the knowledge that is well known in the art does not satisfy the enablement requirements. *When an invention, in its different aspects, involves distinct arts, that specification is inadequate which does not enable the adepts of each art, those who have the best chance of being enabled, to carry out the aspect proper to their specialty.* See *In re Naquin*, 398 F.2d 863,866, 158 USPQ 317, 319 CCPA (1968).

For the above reasons, it is believed that the rejections should be sustained.

Respectfully Submitted,


Dah-Wei D. Yuan
September 8, 2004


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